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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,299	03/16/2004	Randall S. Nelson	1276.006US2	3034

21186 7590 06/21/2004

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EXAMINER

FRISTOE JR, JOHN K

ART UNIT PAPER NUMBER

3754

DATE MAILED: 06/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/801,299	NELSON ET AL.	
	Examiner	Art Unit	
	John K. Fristoe Jr.	3754	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11, 12, 14-16, 19, 23-35, 41-45, 48, 50-52, 54-59 and 61-65 is/are rejected.
- 7) ☒ Claim(s) 10, 13, 17, 18, 20-22, 36-40, 46, 47, 49, 53 and 60 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/16/2004</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 3/16/2004 is acknowledged by the examiner.

Claim Objections

2. Claim 13 objected to because of the following informalities: "galea" is misspelled. Appropriate correction is required.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 19 of U.S. Patent No. 6,726,678.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 19 of U.S. Pat. No. 6,726,678 "anticipates" Application claim 1.

Accordingly, Application claim 1 is not patentably distinct from Patent claim 19.

Here Patent claim 19 requires:

A method comprising

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- Retaining a reservoir for a therapeutic agent between the scalp and the cranium if a subject; and
- Dispensing the therapeutic agent by pumping the therapeutic agent to a location in the subject's body with a pump.

While Application claim 1 requires:

A method comprising

- Retaining a reservoir for a therapeutic agent between the scalp and cranium of a subject.

Thus, it is apparent that the more specific Patent claim 19 encompass Application claim

1. Following the rationale in *In re Goodman* cited in the preceding paragraph, where Applicant has once been granted a patent containing a claim for the specific or narrower invention. Applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer. Note that since Application claim 1 is anticipated by Patent claim 19 and since anticipation is the epitome of obviousness, then Application claim 1 is obvious over Patent claim 19.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 4, 6, 8, 9, 12, 14-16, 26, 27, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Pat. No. 3,310,051 (Schulte). Schulte discloses a method

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comprising retaining a reservoir (20) containing a bladder for a therapeutic agent between the scalp (11) and the cranium (12), refilling the reservoir using a hypodermic needle (36), a port (25) oriented so that the needle is inserted along a line that is generally perpendicular to the plane of the reservoir, the edges of the housing of the reservoir (11) taper from a smaller thickness at the edge to a greater thickness away from the edge (fig. 1), the reservoir outline is imperceptible to a casual observer (fig. 1), wherein the reservoir that is held dimensionally fixed on all axes except one (fig. 1), the reservoir is formed at least in part with silicone (col. 2, lines 63-65), the reservoir is confined by solid surface is a plastic container (col. 2, lines 63-65), wherein the reservoir is of a shape substantially that of the top of a human head (fig. 1), dispensing the therapeutic agent from the reservoir to a location in the brain of a subject (fig. 1), dispensing the agent with a fluid conduit (21) with a proximal end coupled to receive agent from the reservoir and a distal end positioned in the brain of a subject (fig. 1), the reservoir (11) is a pouch and the agent is pumped for the pouch and the pouch collapses as it is emptied maintaining the appropriate pressure volume ratio inside the pouch and thereby preventing air from entering the pouch (col. 2, lines 50-60), and having a sealed silicone portal (col. 2, lines 63-65).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. Claims 2, 3, 19, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 3,310,051 (Schulte) in view of U.S. Pat. No. 6,464,671 (Elver et al.). Schulte discloses the method of dispensing a therapeutic agent but lacks the reservoir being hermetically sealed with a metal. Elver et al. teach a method of hermetically sealing a reservoir in metal foil (col. 4, lines 30-33). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of dispensing a therapeutic agent of Schulte by sealing the reservoir hermetically sealed with a metal as taught by Elver et al. in order to insure that the reservoir stays in a sterile condition.

9. Claims 5 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 3,310,051 (Schulte) in view of U.S. Pat. No. 6,129,685 (Howard, III). Schulte discloses the method of dispensing a therapeutic agent but lacks the reservoir having multiple bladders. Howard, III teaches a method of dispensing therapeutic agents with multiple bladders (147) with multiple connection lines (fig. 25, adjacent element 148). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of dispensing a therapeutic agent of Schulte by having multiple bladders as taught by Howard, III in order to hold multiple types of therapeutic agents under the skin.

10. Claims 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 3,310,051 (Schulte) in view of U.S. Pat. No. 6,190,352 (Haarala et al.). Schulte discloses the method of dispensing a therapeutic agent but lacks the reservoir having a port (20) being oriented is inserted parallel to the reservoir. Haarala et al. teach method of inserting a needle along a line generally parallel (fig. 6) to the reservoir (10). It would

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have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of dispensing a therapeutic agent of Schulte by including a port that allows the needle to be inserted along a line the is generally parallel to the reservoir as taught by Haarala et al. in order to more easily insert the needle into the reservoir.

11. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 3,310,051 (Schulte) in view of U.S. Pat. No. 6,464,671 (Elver et al.) as applied to claim 2 above, and further in view of U.S. Pat. No. 6,129,685 (Howard, III.). Schulte, modified above, discloses a method of dispensing a therapeutic agent with a metal haemostatic seal but lacks having multiple bladders for a reservoir. Howard, III teaches a method of dispensing therapeutic agents with multiple bladders (147) with multiple connection lines (fig. 25, adjacent element 148). It would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the method of dispensing a therapeutic agent of Schulte by having multiple bladders as taught by Howard, III in order to hold multiple types of therapeutic agents under the skin.

12. Claims 28 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 3,310,051 (Schulte) in view of U.S. Pat. No. 6,458,118 (Lent et al.). Schulte discloses the method of dispensing a therapeutic agent but lacks dispensing the therapeutic agent to the spine of the patient. Lent et al. teach a method of pumping a therapeutic agent from an implantable reservoir to the spine of a subject. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of dispensing a therapeutic agent of Schulte by pumping therapeutic agent to the spine as taught by Lent et al. in order to treat an ailment of the spine of a patient with therapeutic agents.

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13. Claims 29, 34, 35, 41, 48, 50, 51, 59, and 61-65 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 3,310,051 (Schulte) in view of U.S. Pat. No. 5,643,207 (Rise). Schulte discloses the method of dispensing a therapeutic agent but lacks having the therapeutic agent dispensed based on programmed parameters and having a power source. Rise teaches a method of dispensing a therapeutic agent with variable timed programmed parameters (32), and a power source (34, 36) having multiple conductors (fig. 3, adjacent element 36) positioned inside the chest of the patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of dispensing a therapeutic agent of Schulte by having an implantable power source and programmed parameters as taught by Rise in order to pump a specific amount of therapeutic agent to the treatment site.

14. Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 3,310,051 (Schulte) in view of U.S. Pat. No. 6,442,433 (Linberg). Schulte discloses the method of dispensing a therapeutic agent but lacks controlling the pump transcutaneously. Linberg teaches a method of controlling an implantable device transcutaneously (col. 10, lines 21-24). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of pumping a therapeutic agent to a treatment site of Schulte by controlling the pump transcutaneously as taught by Linberg in order to control the pump without an invasive procedure.

15. Claims 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 3,310,051 (Schulte) in view of U.S. Pat. No. 5,643,207 (Rise) as applied to claim 41 above, and further in view of U.S. Pat. No. 5,305,745 (Zacouto). Schulte, modified above, discloses a method of dispensing a therapeutic agent with a pump having a power

source but lacks the power source being rechargeable. Zacouto teaches a method of dispensing a therapeutic agent with a pump having a rechargeable power source and recharging the power source transcutaneously (col. 28, lines 21-30). It would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the method of pumping a therapeutic agent to a treatment site of Schulte by having a rechargeable power source as taught by Zacouto in order for the implanted device to be used long term without having to be removed to replace the power source.

16. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 3,310,051 (Schulte) in view of U.S. Pat. No. 5,643,207 (Rise) as applied to claim 51 above, and further in view of U.S. Pat. No. 6,464,671 (Elver et al.). Schulte, modified above, discloses the method of dispensing a therapeutic agent but lacks the reservoir being hermetically sealed with a metal. Elver et al. teach a method of hermetically sealing a reservoir in metal foil (col. 4, lines 30-33). It would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the method of dispensing a therapeutic agent of Schulte by sealing the reservoir hermetically sealed with a metal as taught by Elver et al. in order to insure that the reservoir stays in a sterile condition.

17. Claims 54-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 3,310,051 (Schulte) in view of U.S. Pat. No. 5,643,207 (Rise) as applied to claim 27 above, and further in view of U.S. Pat. No. 6,442,433 (Linberg). Schulte, modified above, discloses the method of dispensing a therapeutic agent but lacks controlling the pump transcutaneously. Linberg teaches a method of controlling an implantable device transcutaneously with a control until that relays status information (col. 10, lines 21-24).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the method of pumping a therapeutic agent to a treatment site of Schulte by controlling the pump transcutaneously as taught by Linberg in order to control the pump without an invasive procedure.

Allowable Subject Matter

18. Claims 10, 13, 17, 18, 20-22, 36-40, 46, 47, 49, 53, and 60 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John K. Fristoe Jr. whose telephone number is (703) 308-1437. The examiner can normally be reached on Monday-Friday, 7: 00 a.m-4: 30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Louis G. Mancene can be reached on (703) 308-2696. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



John K. Fristoe Jr.
Examiner
Art Unit 3754

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6/20/04